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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,204	04/02/2004	Nagi G. Ayad	10498-00067	3911

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,204	AYAD ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-13, 26 drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising an amino acid sequence having at least 60% sequence homology to an amino acid selected from the group consisting of SEQ ID NOs: 1, 2 and 3, wherein the nucleic acid molecule comprising a nucleotide sequence having at least 60% sequence homology to a nucleotide sequence selected from the group consisting of SEQ ID NOs: 4, 5 and 6, wherein the polypeptide has one or more Tome-1 activities; fragments and complements thereof; vectors; cells; a kit; classified in class 435, subclass 69.1, 320.1, 252.3; class 536, subclass 23.5

Should Group I be elected, applicants are required to select one amino acid sequence from claims 1 and 6, and select one corresponding nucleic acid sequence from claims 3, 4 and 5. Each of the polynucleotide and encoded polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **This is not a species election.**

II. Claims 2, 14-19, 23 drawn to an isolated polypeptide comprising an amino acid sequence having at least 60% sequence homology to an amino acid selected from the group consisting of SEQ ID NOs: 1, 2 and 3, wherein the polypeptide has one or more Tome-1 activities; fragments and kit; classified in class 530, subclass 350, 300; class 514, subclass 2.

Should Group II be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18. Each of the polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **This is not a species election.**

III. Claim 20, drawn to an antibody that selectively binds to the polypeptide of any one of claims 14, 16, 17 or 18; classified in class 530, subclass 387.1+.
Should Group III be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one nucleic acid from claim 17. Each of the polynucleotide and encoded polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **This is not a species election.**

IV. Claims 21, 22, drawn to a method for detecting a polypeptide of any one of claims 14, 16, 17 or 18 by using an antibody that binds selectively to the polypeptide; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group IV be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one nucleic acid from claim 17. **This is not a species election.**

V. Claims 24, 25, drawn to a method for detecting the nucleic acid molecule of any one of claims 1, 3, 4, 5 or 6 by using a nucleic acid probe or primer which selectively hybridizes to a complement of the nucleic acid molecule; classified in class 536, subclass 23.1, 24.3, 24.31; class 435, subclass 6.

Should Group V be elected, applicants are required to select one amino acid sequence encoded by a nucleic acid sequence from claims 1, and 6, and one corresponding nucleic acid sequence from claims 3-5. **This is not a species election.**

VI. Claims 27, 28, 29, drawn to a method of identifying a compound that binds to a polypeptide of any one of claims 14, 16, 17 or 18 by contacting said polypeptide with a test compound; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group VI be elected, applicants are required to select one amino

acid sequence from claims 14, 16 and 18, and one corresponding nucleic acid from claim 17.

This is not a species election.

VII. Claims 30, 31, 32 drawn to identifying a compound, and use of said compound that modulates the Tome-1 activity of a polypeptide of any one of claims 14, 16, 17 or 18 by contacting said polypeptide with said compound; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group VII be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one corresponding nucleic acid from claim 17.

This is not a species election.

VIII. Claims 33, 34 drawn for identifying a compound that modulates mitosis, by contacting a polypeptide of any one of claims 14, 16, 17 or 18 with said compound; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group VIII be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one corresponding nucleic acid from claim 17.

This is not a species election.

IX. Claims 35-40, 41 drawn to a method of modulating mitosis in a subject comprising administering to the subject a compound identified in claim 33, wherein said subject is a human, and said compound is an antibody, an antisense molecule, a peptide, or a small molecule, wherein said compound inhibits mitosis; classified in class 536, subclass 23.5; class 530, subclass 300; class 514, subclass 44.

Should Group IX be elected, applicants are required to select one compound from claims 37-40. **This is not a species election.**

X. Claims 35-40, 42 drawn to a method of modulating mitosis in a subject comprising administering to the subject a compound identified in claim 33, wherein said subject is a human, and said compound is an antibody, an antisense molecule, a peptide, or a small molecule, wherein said compound enhances mitosis; classified in class 536, subclass 23.5; class 530, subclass 300; class 514, subclass 44.

Should Group X be elected, applicants are required to select one compound from claims 37-40. **This is not a species election.**

XI. Claim 43, drawn to a method of modulating mitosis comprising contacting a polypeptide of any one of claims 16, 17 or 18 with a compound modulating mitosis; classified in class 536, subclass 23.5; class 530, subclass 300.

Should Group XI be elected, applicants are required to select one amino acid sequence from claims 16 and 18, and one corresponding nucleic acid from claim 17.

This is not a species election.

XII. Claim 44 drawn to a method of modulating mitosis in a cell comprising contacting a cell expressing a poypeptide of any one of claims 14, 16, 17 or 18; classified in class 536, subclass 23.5; class 530, subclass 300; class 514, subclass 44.

Should Group XII be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one corresponding nucleic acid from claim 17.

This is not a species election.

XIII. Claims 45, 46 drawn to a method of modulating mitosis in a subject comprising administering to the subject a nucleic acid of any one of claims 1, 3, 4, 5 or 6, wherein said subject is a human; classified in class 536, subclass 23.5; class 530, subclass 300; class 514, subclass 44.

Should Group XIII be elected, applicants are required to select a nucleic acid sequence from claims 1, 3, 4, 5 or 6. **This is not a species election.**

XIV. Claim 47 drawn for identifying a compound that modulates a Tome-1 activity of a polypeptide of any one of claims 14, 16, 17 or 18, wherein the polypeptide is expressed in a cell comprising contacting said cell with said compound; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group XIV be elected, applicants are required to select one amino acid sequence from claims 14, 16 and 18, and one corresponding nucleic acid from claim 17. **This is not a species election.**

XV. Claims 49-51 drawn to a method of treating a cellular proliferative disorder in subject in need thereof, the method comprising administering to the subject a compound that modulates a Tome-1 activity, wherein said Tome-1 expression is inhibited, wherein said cellular proliferative disorder is cancer; classified in class 536, subclass 23.5; class 530, subclass 300; class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product of Invention II can be made by another materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

nucleic acid of group I is a separate and distinct chemical entity from the antibody of group III. The nucleic acid of Group I does not encode the antibody of Group III and is not used for the practice of Group III. Therefore the inventions are distinct.

Invention I is unrelated to inventions IV, VI, VII, VIII, X, XI, XIV and XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group I is not used for the practice of the methods of groups IV, VI, VII, VIII, X, XI, XIV and XV. Therefore the inventions are distinct.

Invention I and inventions V, IX, XII, XIII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used on another, materially distinct process, such as recombinant production of protein.

The polypeptide of group II is related to the antibody of group III as being the antigen for the antibody. Although the protein and antibody are related, they are distinct inventions. The protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a receptor. Further, the protein of Group II and the antibody of group III are structurally and functionally distinct molecules with different amino acids and different sequences.

Inventions II and IV,V, IX, XII, XIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not necessary for the practice of invention of IV, V, IX, XII, XIII and XV. Therefore the inventions are distinct.

Invention II is related to inventions VI, VII, VIII, X, XI and XIV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II has demonstrated different processes of use as set forth in the claims of Groups VI, VII, VIII, X, XI and XIV.

Invention III is related to inventions IV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group III can be used on another, materially distinct process, such as affinity chromatography.

Invention III and inventions V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of III is not necessary for the practice of inventions of IV, V, VI, VII, VIII, IX, XI, XII, XIII and XIV. Therefore inventions are distinct.

Invention IV and inventions V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of IV is not necessary for the practice of inventions V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV. Therefore the inventions are distinct.

Inventions V, IX, XII, XIII, XV and inventions VI, VII, VIII, X, XI, XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of V, IX, XII, XIII, XV is not necessary for the practice of inventions VI, VII, VIII, X, XI, XIV. Therefore the inventions are distinct.

Inventions V, IX, XII, XIII and XV are related by virtue of the nucleic acid which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions VI, VII, VIII, X, XI and XIV are related by virtue of the polypeptide, which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions VI and inventions IX, XII, XIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of VI is not necessary for the practice of inventions IX, XII, XIII and XV. Therefore the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.
March 20, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER